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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,706	04/16/2002	Camilo Anthony Leo Selwyn Colaco	8830-23	7593

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,706	COLACO, CAMILO ANTHONY LEO SELWYN	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JM

DETAILED ACTION

Applicants amendment filed December 20, 2004 has been received and entered. Claims 1-18 and 20-22 are pending in the instant application, of which claims 1-13 and 20-22 have been withdrawn from further consideration as being drawn to a non-elected invention.

Applicants attention is drawn to the listing of the claims filed December 20, 2004 and note that claim 19 is not listed. In order to be fully responsive, every claim must be recited consecutively and its status identified. For instance claim 19 should be listed and its status (canceled) should be recited. Appropriate correction is required.

Election/Restrictions

Applicants have requested reconsideration and withdrawal of the lack of unity objection as to all claim groups. Applicants assert that the cited prior art which allegedly defeats unity of invention does not disclose or suggest that cells in which trehalose production has been induced may be more immunogenic than non-induced cells. Applicants further assert that the cells of the present invention as claimed do not need to be dried, they also do not need to be stabilized.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the cited prior art does not disclose or suggest that cells in which trehalose production has been induced may be more immunogenic than

non-induced cells. However, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Second, Applicants further assert that the cells of the present invention as claimed do not need to be dried, they also do not need to be stabilized. However, the question is not whether they need to be dried or not, but do the claims encompass such limitations? Given that the claims do not exclude such steps as drying, this argument is not germane.

This restriction is still deemed proper and its Finality is maintained.

This application contains claims 1-13 and 20-22 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

1. The rejection of claims 14-18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of trehalose synthesis in some strains (i.e., E. coli and Salmonella typhimurium) of bacteria and production of antibodies in animals against said strains, does not reasonably provide enablement for a vaccine is withdrawn.

2. The rejection of claims 15 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 14-18 under 35 U.S.C. 102(b) as being anticipated by Tunnacliff et al is maintained.

Applicants are asserting that the cited prior art does not disclose or suggest that cells that have been induced to increase trehalose production may be more immunogenic than non-induced cells. Applicants further assert that the step of drying the cells using a drying medium in which trehalose is present is not required in the present invention.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that the cited prior art does not disclose or suggest that cells that have been induced to increase trehalose production may be more immunogenic than non-induced cells. However, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the

discoverer." *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Finally, Applicants assert that the step of drying the cells using a drying medium in which trehalose is present is not required in the present invention. However, Applicants are respectfully directed back to the claims. Claim 14 recites "A vaccine composition compising an immunogenic determinant, wherein the immunogenic determinant includes a prokaryotic cell or cell residue which contains at least 10mM of trehalose within the cell. Tunnacliff et al disclose of a vaccine composition comprising a prokaryotic cell which contains at least 10mM of trehalose within the cell. Accordingly, each and every limitation has been addressed.

Tunnacliff et al (WO 98/24882) disclose of a vaccine composition comprising a prokaryotic cell, which contains at least 10 mM of trehalose within the cell. (See pages 6, 13, 21 and claims). Turnacliff et al further disclose of adjuvants, drying in the presence of non-reducing carbohydrates. (see pages 14, 21 and claims).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 14-18 under 35 U.S.C. 102(e) as being anticipated by Tunnacliff et al (US Patent 6,468,782) is maintained.

Applicants assertions are identical to those recited above in paragraph number 3, and have been fully addressed in paragraph number 3.

Accordingly, this rejection is maintained for reasons of record, as well as the reasons set forth above in paragraph number 3.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
March 30, 2005